

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference W 5695-006	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2004/001001	International filing date (day/month/year) 23.06.2004	Priority date (day/month/year) 26.06.2003
International Patent Classification (IPC) or national classification and IPC A61K 31/045, A61K 09/06, A61P 31/04 // A01N 31/02		
Applicant Ambria Dermatology AB et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 31.03.2005	Date of completion of this report 27.09.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88 Form PCT/IPEA/409 (cover sheet) (April 2005)	Authorized officer Eva Johansson/EÖ Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001001

Box No. I Basis of the report

1. With regard to the language, this report is based on:



the international application in the language in which it was filed



a translation of the international application into _____, which is the language of a translation furnished for the purposes of:



international search (Rules 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:



the international application as originally filed/furnished



the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing (*specify*): _____



any table(s) related to the sequence listing (*specify*): _____

4. ☐

This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing (*specify*): _____



any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001001

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1 - 4

because:

☒ the said international application, or the said claims Nos. 1 - 4
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv) : Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001001

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>5-18</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>5-18</u>	NO
Industrial applicability (IA)	Claims	<u>5-18</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are cited in the International Search Report are:

D1 WO 0107003 A1

D2 WO 9015597 A1

D3 Zadeh, Hossein Sedghi, et al "Inhibitors of microbial growth. Limits and efficacy" Cosmetic Technology (Milano Italy), 2001, 4(3), pages 43-48.

D4 EP 1166762 A1 (page 5 paragraph [0038] table 1)

D5 WO 93 20812 A1

D6 US 5879690 A1

D7 US 5550145 A1

The problem to be solved by the present application is to find a method for inhibiting the growth of multiple-resistant bacteria. This is solved by using a composition comprising 15% of weight or more of pentane-1,5-diol.

D1 discloses a cosmetic composition comprising elastomer, siloxane, water and from 0.1 to 40% by weight of pentylene glycol. The composition is an elastomer emulsion with improved phase stability as a result of the presence of pentylene glycol. The composition is also microbiologically preserved through the addition of pentylene glycol. No other traditional preservatives are needed (see particular page 11 lines 7-10). The addition of pentylene glycol is from 0.1 to 40% by weight, preferably from 0.8 to about 20%, and optimally from 1 to 8% by weight. On page 10 lines 16-18 it is said that "preservatives can desirably be incorporated into the

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

compositions of this invention to protect against the growth of potentially harmful micro organisms".

D2 discloses a preparation for topical treatment of infections caused by virus, bacteria and fungi. The preparation contains pentane diol or hexane diol as active substance. Pentane-1,5-diol is preferred as active substance in the composition. In one example pentane-1,5-diol is diluted in ethanol to give a solution containing 50% diol and 50% ethanol. Other solvents for the diol are water or ether. The concentration of the diol can vary from a high dilution to a concentrated form. From D2, it is also shown that pentane-1,5-diol is active against *Staphylococcus aureus*, one of the mentioned bacteria in the application.

D3 discloses different cosmetic compositions and to protect these against the growth of micro organisms, pentylene glycol is added to the compositions. Pentylene glycol is defined as an agent against micro organisms in table 1 and table 2.

D4 discloses compositions containing mineral water. From the description on page 5 paragraph 0039, it is said that the compositions might also comprise antioxidants and preservatives. As a preservative, pentylene glycol is used with a weight % of 20 (table 1, page 6).

D5 discloses an antimicrobial composition which contains pentylene glycol. Pentylene glycol is used to preserve the product against microbial contamination and to use the product in the treatment of antimicrobial infections.

D6 and D7 disclose the general state of the art and are not considered to be particular relevant.

The claimed invention is not disclosed from D1-D7, thus the invention in claims 5-18 is novel.

Document D1, which is considered to represent the most relevant state of the art, which solves the same problem as the claimed invention, differs in that it is a cosmetic

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

composition instead of a pharmaceutical composition and that the highest weight % of pentylene glycol is 10. There is no information in the application that 15% by weight of pentan-1,5-diol (pentylene glycol) solves a different problem than 10% by weight of pentan-1,5-diol in D1.

The problem to be solved is inhibiting the growth of multiple-resistant bacteria. This is solved by using a composition comprising 15% of weight or more of pentane-1,5-diol.

D2 shows that pentane-1,5-diol is active against *Staphylococcus aureus* one of the mentioned bacteria in the application and can be used in higher concentration than 15%.

To a person, who is acquainted with diols and their use as preservatives and antimicrobials, and with knowledge from D1 and D2, it would be obvious that a composition comprising 15% of weight or more of pentane-1,5-diol will solve the problem of inhibiting the growth of multiple-resistant bacteria.

Thus, claims 5-18 lack inventive step.